IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: HUMAN TISSUE PRODUCTS LIABILITY LITIGATION	)	(Electronically Filed)
	)	Docket No. 2:06-cv-00135 (WJM/RJH)
This Document Relates to: All Cases	)	MDL – 1763
	)	Return Date: December 27, 2006

BRIEF OF REGENERATION TECHNOLOGIES, INC.
IN OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL

I. PRELIMINARY STATEMENT

Regeneration Technologies Inc.'s ("RTI") "Science First motion" presents a very simple position: RTI's tissue allografts sterilized to sterility assurance level ("SAL") 10^{-6} are incapable of transmitting disease. The Court has directed plaintiffs to first address the question of whether tissue which has been sterilized to SAL 10^{-6} is capable of transmitting disease. In doing so, plaintiffs are to assume that RTI's processes achieve sterilization of SAL 10^{-6}.

Plaintiffs requested and were granted a second opportunity to address what discovery they need to respond to this question only. In response, plaintiffs submitted a motion to compel. Rather than explain the relevancy of the requested discovery to the question posed by the Court, plaintiffs resort to baseless accusations that the defendants have withheld documents. While the discovery sought is not relevant to what is a pure science issue, RTI has already produced the documents requested. Plaintiffs' motion to compel should therefore be denied and plaintiffs should be required to respond to the question posed by January 19, 2007.

II. BACKGROUND

The Science First motion was jointly filed by RTI and Medtronic on October 20, 2006. The Science First motion addresses two threshold science questions: 1) whether tissue sterilized to SAL 10^{-6} is incapable of transmitting disease; and 2) whether RTI's Biocleanse® and bone paste processes are validated sterilization processes that achieve SAL 10^{-6}. The defendants' scientific experts have answered both questions in the affirmative. Since RTI's sterilized allografts are incapable of transmitting disease, there is no scientific basis for the plaintiffs' complaints and they should be dismissed with prejudice.

Plaintiffs were not required to answer the Science First motion but instead were given five weeks to determine what discovery, if any, they needed to respond to the motion. In addition, a court conference was scheduled to discuss plaintiffs' requests. By letter, dated November 27, 2006, plaintiffs identified four categories of documents which they claimed RTI had not produced: (1) substantive documentation relating to RTI's BioCleanse® process; (2) documents relating to RTI's donor acceptance criteria; (3) quality control documents; and (4) calibration and maintenance records.

During the court conference on November 28, 2006, RTI reported to the Court that all four categories of documents had already been produced. In fact, in September 2006, RTI had produced all materials provided to the defendants' experts which were substantive documents on RTI's Biocleanse® and bone paste sterilization process (approximately 1,000 pages). RTI specifically identified those materials by bates number at plaintiffs' request in a letter of November 1, 2006. (*See* Court Transcript of 11/28/06, Docket No. 177 ("11/28 Tr.") at 41:4-7; *see also* November 1, 2006 letter attached as Exhibit "1" to Declaration of Denise Brinker Bense ("Declaration").) In addition, RTI had already produced documents regarding donor acceptance

criteria (11/28 Tr. 41:8-18), 15,000 pages relating to quality control (*id*. 41:25 -42:1) and 17,000 pages relating to calibration. *Id*. 41:22-25.

It was apparent at the November 28th hearing and in the current motion to compel (which is their second opportunity) that plaintiffs' real objection is not a lack of discovery needed to respond to the Science First motion, but that their disagreement with the Court's decision to address the Science First motion at all. Plaintiffs hope to delay a response until they have an opportunity to conduct discovery on issues that have nothing to do with the science issues at hand.

Predictably, plaintiffs still have not identified any documents, or any discovery, which need to be produced before they respond to the first science question posed by the Court. Plaintiffs' position that this question "cannot be determined at this stage of the litigation" is without support. Motion to compel at 7. In an attempt to challenge RTI's Biocleanse® process, plaintiffs rely upon RTI's use of the term "passivation" in its 2002 patent application and question whether the process was properly implemented. Neither the patent application nor the process implementation is relevant to the inquiry posed by the Court – whether tissue sterilized to SAL 10^{-6} is capable of transmitting disease.

True to form, plaintiffs' motion to compel requests documents that RTI has already produced. The RTI documents listed by plaintiffs fall within three categories: (1) Biocleanse® and bone paste sterilization process materials submitted to the defense experts, produced to plaintiffs in September 2006 and specifically identified in RTI's letter of November 1, 2006; (2) Standard Operating Procedure materials; and (3) FDA and State materials relating to the pooling of tissue and the approval of BioCleanse® and bone paste sterilization processes.[1]

[1] Five of the twenty-one documents listed are directed to Medtronic.

As set forth in detail below, thousands of documents have been produced by RTI in these categories. To date, RTI has produced over 100,000 pages of documents in OCR searchable format and its production will continue until all documents relevant to the issues in the litigation have been produced. RTI's ongoing production, however, is not relevant to the first question plaintiffs must answer.

ARGUMENT

III. NO DISCOVERY WAS NECESSARY FOR PLAINTIFFS TO RESPOND TO THE QUESTION OF WHETHER TISSUE STERILIZED TO SAL 10^{-6} IS CAPABLE OF TRANSMITTING DISEASE.

Whether tissue sterilized to SAL 10^{-6} is capable of transmitting disease is a pure "science" issue. While plaintiffs bear the burden, defendants have provided the Court with indisputable evidence from five renowned scientific experts that plaintiffs cannot establish they were exposed to disease by RTI's tissue allografts which are sterilized to SAL 10^{-6}.

Plaintiffs' position that the Science First motion involves "novel and controversial scientific issues" and that RTI has "a virtual monopoly" on science and information in its "sole possession" is without merit. There is no debate in the scientific community that tissue allografts sterilized to SAL 10^{-6} are incapable of transmitting disease. If plaintiffs dispute this point, they must present a scientific expert to do so. No discovery from RTI is needed to answer this question. Regardless, RTI has already produced the discovery outlined in plaintiffs' motion to compel as follows:

1. Biocleanse® and Bone Paste Sterilization Process Materials Submitted to Defense Experts.

Plaintiffs' Motion to Compel Requests

- *All documentation, research and tests connected with the development of the BioCleanse process, including the process specification that was developed consequent to the validation studies*
- *All documentation of the SAL obtained by the BioCleanse process*

RTI Produced

In September 2006, RTI produced from its IKON hard copy collection a total of at least 1000 pages of documents relating to the first general category of documents requested by Plaintiffs which relate to Biocleanse® and bone paste sterilization process materials submitted to the defense experts**.** By letter dated November 1, 2006, RTI specifically identified these documents by Bates Number. *See* Declaration, Exhibit "1."

Validation of BioCleanse Process (RTI0003302-3309);

Summary Report Validation of the BioCleanse Universal Recipe Dye Perfusion (RTI0004209-4222);

BioCleanse Tissue Processing System Biocompatibility Volume I (RTI0004223-4383);

BioCleanse Tissue Processing System Validation Master Plan (RTI0004384-4510)

BioCleanse Tissue Processing System Biocompatibility Volume II (RTI0004511-4538)

Validation Report BioCleanse Tissue Processing System Dye Perfusion (RTI0004575-4601)

Validation Report BioCleanse Tissue Sterilization Process Sporicidal Efficacy (RTI0004602-4633)

Summary Report Qualification of the BioCleanse Tissue Processing Systems (RTI0004634-4640);

Summary Report Validation of BioCleanse Universal Recipe Spore Spike Injection (RTI0004641-4655)

RTI's Premarket Notification Submission Table of Contents (RTI0008778-8779)

Sections from RTI's 510(k) (Bates RTI00010420-10737 and RTI00009117-9156).

Plaintiffs' Motion to Compel Requests

- *Viral inactivation studies performed by RTI*
- *Any and all studies where BioCleanse was implemented on bone where virus concentrations were high in the canaliculi and findings regarding same*
- *Procedures for inoculating the haversian and volkman canals, the lacunae, and canaliculi of human allograft with bacteria and virus so as to prove that such contaminates can be eliminated using BioCleanse (this request also includes all studies of osteon penetration by sterilants and studies confirming same)*

- *All documentation, research and tests regarding microorganism inactivation by the BioCleanse process*

RTI Produced

As part of its expert materials, RTI previously produced:

Final Report, Evaluation of Human Immunodeficiency Virus Inactivation by BioCleanse process for Bone Tissue Homogenate (RTI0003453-3476)

Validation Report BioCleanse Tissue Processing System Viral Clearance (RTI00023350-23464)

Guidance for Industry Viral Safety Evaluation (RTI00010387-10419)

Validation Report BioCleanse Tissue Processing System Antimicrobial Capacity of Germicide Within Cortical Bone and Soft Tissue Matrices (RTI0007367-7392)

Validation Report BioCleanse Tissue Processing System Antimicrobial Capacity Scaled Model (RTI0007502-7511)

Validation Procedure Antimicrobial Capacity of the BioCleanse Tissue Processing System (RTI0023494-23499)

Validation Report BioCleanse Tissue Sterilization Process Antimicrobial Capacity Septic Tissue Model (RTI0004539-4574)

Plaintiffs' Motion to Compel Requests

- *All documentation of validation of BioCleanse process for Prions and Mad Cow Disease*

- *Any and all studies/finding showing BioCleanse's effect on allographs with known cancer cells*

RTI Produced

RTI has previously produced approximately 158 pages relating to this subject matter.[2]

2. Standard Operating Procedures Materials.

Plaintiffs' Motion to Compel Requests

- *All documentation explaining how RTI screened for old/aged bone and in-house process for testing the performance characteristics/physical attributes of bones.*

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[2] The page count totals cited in RTI's Opposition were obtained by running a simple query on the OCR searchable text provided to plaintiffs by RTI.

- *All documentation setting forth safe guards to prevent cross contamination.*
- *All documentation detailing the radiation process utilized by RTI*

RTI Produced

RTI has produced at least 300 pages relating to screening and performance of bone. RTI has produced at least 520 documents relating to cross contamination. RTI has produced at least 579 documents detailing the radiation process utilized by RTI.

Plaintiffs' Motion to Compel Requests

- All *documentation regarding any additional steps that certain types of grafts may go through after the sterilization process.*
- *All documentation of the internal policies and procedures necessary to ensure the validated sterilization process was followed with every allograft.*

RTI Produced

With regard to the steps any additional steps that certain types of allografts may go through after the sterilization process, the "donor information files" produced to date include the donor's individual manufacturing files which contain documents relating to each step the plaintiff's particular tissue was subjected to from the time it was received by RTI until it was cleared for distribution. These files total approximately 27,000 pages. In addition, RTI has produced at least 3,366 pages of documents relating to standard operating procedures apart from those specified above.

3. FDA and State materials relating to the pooling of tissue and the approval of BioCleanse® and bone paste sterilization processes .

Plaintiffs' Motion to Compel Requests

- *Letter from FDA in May 2001 expressing concerns with safety and validation of RTI's BioCleanse process*
- *All documentation regarding practice of pooling*
- *Letter from FDA validating RTI's sterilization processes*

- *All data, analysis and reports RTI sent to the FDA regarding the recall and subsequent testing of individuals who received tainted implants*

RTI Produced

RTI has not only produced the May 3, 2001 letter and the correspondence thereafter which concluded with the FDA's favorable review of Biocleanse® in January 2002. (See RTI00042011-42013; RTI00042040-42042; RTI0030127-RTI-0030129; RTI029932 and RTI023962; RTI00029925-29926). These inquiries and approval by the FDA involved a review of the pooling issue. Documents relating to this inquiry as well as others documents relating to the pooling issue total approximately 350 pages In addition, RTI has produced documents relating to RTI's 510K submissions and the FDA's response.[3]

IV. RTI HAS PRODUCED OVER 100,000 PAGES TO DATE AND CONTINUES TO PRODUCE RELEVANT DOCUMENTS ON AN AVERAGE OF 6,000 PAGES PER WEEK .

Plaintiffs protest regarding the pace and substance of RTI's discovery is unfounded. The focus of plaintiffs' motion to compel is their dissatisfaction with being unable to serve "formal" discovery and their argument that RTI was ordered on July 31, 2006 to produce, within 90 days, 2.5 million pages of electronically stored information ("ESI"). This is simply not accurate.

On July 31, 2006, RTI's counsel reported to the Court that they had collected and preserved approximately 200,000 pages of hard copy documents and 2.5 million pages of ESI from the hard drives of 34 custodians. The Court ordered RTI to review the documents for privilege and to begin to produce the relevant documents on a rolling basis. *See* Court Transcript of 7/31/06, Docket No. 46 ("7/31 Tr.") at 36:7-25. RTI expected to first review and produce "donor information files" for the named plaintiffs in federal and state court and would then

[3] RTI has also produced 726 documents relating to correspondence RTI sent to the FDA regarding the recall and subsequent testing of individuals. Additionally, the FDA's clearance letter for RTI's 12/04 submission is scheduled to be produced in RTI's next production.

review and produce from its hard copy collection. Thereafter, it would turn to the ESI collection. *Id.*, 38:13-39:24.

On October 5, 2006, the Court ordered RTI to collect the network ESI for the 34 designated custodians in the time frame of January 1, 2000 (which was two years prior to the first date in the New York indictment and which is more than two years before RTI received any tissue from BTS) to November 18, 2005 (the date of the first law suit filed) and to report on the status of the collection on November 6, 2006. *See* PTO-3, ¶2. RTI and plaintiffs were to agree to terms to be used to search the 34 custodians hard drive and network collections. The parties were unable to agree and a court conference was scheduled for November 13, 2006.

On November 13, 2006, over RTI's objection, the Court ordered that plaintiffs' 150 search terms be used along with the January 1, 2000 to November 18, 2005 time period to search the hard drive and network of the 34 custodians collected. Applying this criteria to just the 2.5 million pages in the 34 custodians hard drives resulted in "hits" of approximately 1 million pages to be reviewed for potential production. RTI was directed to begin its review of ESI, while continuing in its production of the donor information files for named plaintiffs, giving priority to the federal plaintiffs, as well as its production from the hard copy collection.

RTI's production began on August 24, 2006. In less than four months time, RTI has produced over 100,000 pages of documents. RTI has produced 27,500 pages of "donor information files" for 227 named plaintiffs in federal and state courts which include: (1) donor files; (2) preprocessing documents; (3) manufacturing files; and (4) Tissue Utilization Records. Contrary to plaintiffs assertion that they do not have documents which reflect "the processing cycle of the very bones at issue in this litigation", the individual donor manufacturing files track RTI's receipt and processing of each piece of tissue from each donor. Motion to compel at 12.

Of the remaining 117 named plaintiffs in state and federal court, 84 plaintiffs have not provided RTI with tissue identifying information. RTI is collecting data on the final 33 plaintiffs.

The approximately 73,000 pages produced from the hard copy collection include relevant RTI validation studies and protocols, standard operating procedures, processing and quality control documents, calibration and maintenance records and FDA and State related materials. RTI has produced 1561 pages from its ESI collection, but has reviewed more than 11,600 pages in just three weeks.

Plaintiffs' attempt to increase the number of ESI custodians to be reviewed from 34 to 70 should not be permitted. Plaintiffs' claim that RTI is not "willingly producing custodian files for key individuals that worked at RTI during the relevant time periods contained in plaintiffs' complaints" and base this accusation on their "recent" receipt of FOIA documents.

The relevant time period in this litigation is from May of 2002 when RTI first received BTS tissue through October of 2005 when the recall occurred. While plaintiffs just received the FOIA response, the 1999 and 2000 FDA inspection reports were previously produced by RTI. The time frame chosen by the Court of January 1, 2000 through November 18, 2005 is appropriate. Plaintiffs' expansion of the number of custodians or time is just another effort to increase RTI's time and costs.

V. RTI's FORM OF PRODUCTION HAS BEEN PREVIOUSLY ADDRESSED AND APPROVED BY THE COURT.

At the first MDL court conference in this case on July 31, 2006, the Court ordered all defendants' production whether originating from hard copy or ESI, to be in searchable format. 7/31 Tr. 37:18-24; 47:8-20. Plaintiffs have raised the question of native format at almost every court conference and this Court again rejected plaintiffs' request that production be in native format with all metadata during the Court conference on November 13, 2006. RTI has produced all of its documents in accordance with this Court's Order in electronic format in single page

TIFFs, Group 4 at 300 DPI, with a load file that includes OCR searchable format which reflects the beginning and end Bates number.

CONCLUSION

For these and all the reasons enumerated above, it is respectfully requested that plaintiffs' motion to compel be denied in its entirety.

Respectfully submitted,

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